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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/727,124

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Francisco Arias

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MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C

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EXAMINER

VARGOT, MATHIEU D

ART UNIT

PAPER NUMBER

1732

MAIL DATE

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10/01/2007

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/727,124

Applicant(s)

ARIAS ET AL.

Examiner

Mathieu D. Vargot

Art Unit

1732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8-17 is/are rejected.
- 7) ☒ Claim(s) 6 and 7 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/16/07</u> .   | 6) <input type="checkbox"/> Other: _____                          |

1.Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 10, the followings lack antecedent basis—"said independent microstructure layer" (line 2) and "said microstructure layer" (line 3). Also, it is not at all clear what the "independent microstructure layer" and "said microstructure layer" are—apparently, if they are one in the same, they are not the photoresist. Clarification is required.

2.The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Prausnitz et al.

Prausnitz et al (see the passage bridging columns 21 and 22) discloses the instant process of fabricating microneedles—ie, the mold itself-- using the instant steps to make a microneedle structure—ie, the mold—which would constitute a plurality of solid protrusions. The patterned photoresist is in fact separated from the substrate, thereby creating a microneedle structure from said patterned photoresist material..." as set forth in claim 1 (ie, claim 1 does not positively recite that the photoresist material is in fact the microneedle structure itself). Since claim 1 does not contain any recitations that

exclude the mold as constituting the microneedle structure, it is respectfully submitted that these claims are anticipated by the applied reference.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-5 and 8-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prausnitz et al generally for reasons of record noting the following.

It is maintained that the use of a soft imprint lithography method is obvious over the molding taught in Prausnitz et al. In particular, see column 19, line 7, which teaches "embossing or injection molding". The embossing would certainly be akin to soft lithography, which **is in fact** embossing a moldable material during a lithographic process, the latter already taught in the applied reference. Note that the aspect of having two resists was already indicated as obvious over the single resist of the applied reference dependent on the exact etching performed and microneedle structure desired. The use of more than one resist is conventional in the art to allow the product to be tailored as desired. Also, Prausnitz et al teaches a sacrificial layer between the substrate and the resist and employing one that is acid-dissolvable would certainly have been within the skill level of the art since acids are conventionally used as etching agents. The SU-8 epoxy resist is taught in the applied reference. The exact aspect ratio of the individual microneedles in the microneedle structure would have been well within the skill level of the art dependent on exact use for the microneedles. To the

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extent that claim 10 is understood—ie, “said independent microstructure layer” lacks antecedent basis and hence it is unclear exactly what applicant intends this to be—it is believed that such constitutes an obvious modification to the process of the applied reference if such is not already taught. Prausnitz et al discloses molds that have an electroplated layer and would constitute an independent microstructure layer. Again, applicant is requested to provide clarification as to exactly what is being claimed in instant claim 10. Instant claim 11 involves an additional step of using a first product as a mold in a subsequent molding operation. Applicant should be well aware that such is conventional in the art and routinely done dependent on the exact final product configuration desired. Such would not constitute a patentable advance in the art over Prausnitz et al. Prausnitz et al discloses forming holes in the microneedles and polishing or grinding would be a conventional way of doing this. Applying an electrically conductive substance onto the microneedle structure would have been an obvious feature in the process of the applied reference so that the structure would be electrically addressable—this is rather conventional in the medical art. Hardening the tip would have been an obvious expedient so that the tip pierces the skin more easily. While the applied reference does not show a break away microneedle structure, Figure 9 therein shows the structure attached to the skin. Making the needle portion a “break-away—structure would obviate having to tape the base portion to the skin.

4. Applicant's arguments filed July 16, 2007 have been fully considered but they are not persuasive. Upon closer review, it is submitted that claims 1 and 2, while arguably obvious over Prausnitz et al, **are in fact anticipated by the reference.**

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Applicant's comments concerning the use of a soft lithography to make the microneedles are not well founded, particularly since the reference discloses embossing as a way to pattern the molded material against the mold. Soft lithography involves such a step. Claim 10, while the dependency was changed, still includes language that lacks antecedent basis.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mathieu D. Vargot whose telephone number is 571 272-1211. The examiner can normally be reached on Mon-Fri from 9 to 6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson, can be reached on 571 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Vargot  
September 26, 2007

  
Mathieu D. Vargot  
Primary Examiner  
Art Unit 1732

9/26/07